

Protocol Number: NIDA-CPU-0002

GBR 12909 for Cocaine Dependence

Site Identification Number: 000001

Subject Identification Number: 0001

Study Day: UNSCHD

ADVERSE EVENTS

Has the subject had any Adverse Experiences during this study?

Yes No

If yes, please list all Adverse Experiences below:

Table with 6 columns: Severity, Study Drug Relationship, Action Taken Regarding Investigational Agent, Other Action Taken, Outcome of AE, Serious. Includes legend for severity levels and serious status.

Main table for recording adverse events with columns: #, EVENT, Start Date, Stop Date, Sev., Drug Rel., Action Taken, Other Action, Out., Serious, Initials.

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Date: (mm/dd/yyyy)

Form Not Done

ALCOHOL BREATHALYZER TEST

1) Was alcohol breathalyzer test performed? Yes No Unknown

2) Date test performed: (mm/dd/yyyy)

3) Blood Alcohol content (BAC): (mg/ml)

4) Provide comment for any action taken:

Source Completed By (Initials):

ALBREATH v1

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Form Not Done

Date: (mm/dd/yyyy)

BRIEF SUBSTANCE CRAVING SCALE (BSCS)

1) The INTENSITY of my craving, that is, how much I desired cocaine in the past 24 hrs was: []

2) The FREQUENCY of my craving, that is, how often I desired cocaine in the past 24 hrs was: []

3) The LENGTH of time I spent in craving for cocaine during the past 24 hrs was: []

4) Write in the NUMBER of times you think you had craving for cocaine during the past 24 hours: []

5) Write in the total TIME spent craving cocaine during the past 24 hours: [] HOURS [] MINUTES

6) WORST day: During the past week my most intense craving occurred on the following day: []

7) The date for that day was: [] (mm/dd/yyyy) (If All days the same, then skip to Question #8)

8) The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was: []

9) A 2nd craved drug during the past 24 hours was: []

[] Other (specify)

10) The INTENSITY of my craving, that is, how much I desired this second drug in the past 24 hrs was: []

11) The FREQUENCY of my craving, that is, how often I desired this second drug in the past 24 hrs was: []

12) The LENGTH of time I spent in craving for this second drug during the past 24 hrs was: []

13) A 3rd craved drug during the past 24 hours was: []

[] Other (specify)

14) The INTENSITY of my craving, that is, how much I desired this third drug in the past 24 hrs was: []

15) The FREQUENCY of my craving, that is, how often I desired this third drug in the past 24 hrs was: []

16) The LENGTH of time I spent in craving for this third drug during the past 24 hrs was: []

Source Completed By (Initials) []

BSCS v1

Protocol Number: NIDA-CPU-0002

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CONCOMITANT MEDICATIONS

Has the subject taken any Concomitant Medications during this study?

Yes No

If yes, please list all below:

Table with 4 columns: Dose, Unit of Medication, Frequency, and Route of Administration. It lists various units (e.g., capsule, puff, gram, spray/squirt), frequencies (e.g., single dose, once daily, twice daily), and routes (e.g., oral, auricular, transdermal, intra-articular).

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Site Identification Number: 980101

Subject Identification Number: 0001

Study Day DAY0

Form Not Done

Date:
(mm/dd/yyyy)

CHANGES IN SEXUAL FUNCTIONING QUESTIONNAIRE (CSFQ-Female)

- 1) Compared with the most enjoyable it has ever been, how enjoyable or pleasurable is your sexual life right now?
- 2) How frequently do you engage in sexual activity (sexual intercourse, masturbation, etc.) now?
- 3) How often do you desire to engage in sexual activity?
- 4) How frequently do you engage in sexual thoughts (thinking about sex, sexual fantasies) now?
- 5) Do you enjoy books, movies, music or artwork with sexual content?
- 6) How much pleasure or enjoyment do you get from thinking about and fantasizing about sex?
- 7) How often do become sexually aroused?
- 8) Are you easily aroused?
- 9) Do you have adequate vaginal lubrication during sexual activity?
- 10) How often do you become aroused and then lose interest?
- 11) How often do you experience an orgasm?
- 12) Are you able to have an orgasm when you want to?
- 13) How much pleasure or enjoyment do you get from your orgasms?
- 14) How often do you have painful orgasm?

Source Completed By (Initials):

TOTAL SCORE:

CSFQFEML v1

Protocol Number: NIDA-CPU-0002

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day DAY0

Form Not Done

Date:
(mm/dd/yyyy)

CHANGES IN SEXUAL FUNCTIONING QUESTIONNAIRE (CSFQ-Male)

- 1) Compared with the most enjoyable it has ever been, how enjoyable or pleasurable is your sexual life right now?
- 2) How frequently do you engage in sexual activity (sexual intercourse, masturbation, etc.) now?
- 3) How often do you desire to engage in sexual activity?
- 4) How frequently do you engage in sexual thoughts (thinking about sex, sexual fantasies) now?
- 5) Do you enjoy books, movies, music or artwork with sexual content?
- 6) How much pleasure or enjoyment do you get from thinking about and fantasizing about sex?
- 7) How often do you have an erection related or unrelated to sexual activity?
- 8) Do you get an erection easily?
- 9) Are you able to maintain an erection?
- 10) How often do you experience painful prolonged erections?
- 11) How often do you have an ejaculation?
- 12) Are you able to ejaculate when you want to?
- 13) How much pleasure or enjoyment do you get from your orgasms?
- 14) How often do you have painful orgasm?

Source Completed By (Initials):

TOTAL SCORE:

CSFQMALE v1

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Study Day UNSCHD

Site Identification Number: 000001

Subject Identification Number: 0001

DEATH REPORT

Subject Date of Death (mm/dd/yyyy)

Was autopsy performed? Yes No Unknown

If yes, is autopsy report available? Yes No

Is cause of death known? Yes No

If yes, in the investigator's clinical judgement, what was the primary cause of death?

Narrative description of death (include information about why cause of death is unknown, if applicable.)

Source Completed By (Initials):

DEATH v1

Protocol Number: NIDA-CPU-0002

GBR-12909 for Cocaine Dependence

Study Day UNSCHD

Site Identification Number: 000001

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Form Not Done

DEMOGRAPHICS

DEMOGRAPHIC DATA

- 1) Gender Male Female
2) Date of Birth (mm/dd/yyyy)

3) Indicate which single major race/ethnicity applies:

- White, not of Hispanic Origin
Hispanic or Latino
African American, Black, not of Hispanic Origin
Asian or Pacific Islander
American Indian or Alaska native
Other, (specify):
Unknown

4) Ethnicity/Race all that apply:

For each of the following, answer Yes to all that apply and No to those that do not.

- Yes/No White
Yes/No Black, African American, or Negro
Yes/No American Indian or Alaskan Native
Yes/No Spanish, Hispanic, or Latino (mark all that apply)
Mexican, Mexican-American, or Chicano
Puerto Rican
Cuban
Other (specify)
Yes/No Asian (mark all that apply)
Asian Indian
Chinese
Filipino
Japanese
Korean
Vietnamese
Other (specify)
Yes/No Native Hawaiian or Pacific Islander (mark all that apply)
Native Hawaiian
Guamanian or Chamorro
Samoan
Other (specify)
Other (specify)
Participant chooses not to answer

EMPLOYMENT/SUPPORT STATUS

1) Education completed (GED = 12 years): (years) (months)

2) Usual employment pattern, past 30 days:

- 1 - Full time (35+ hours/week)
2 - Part time (regular hours)
3 - Part time (irregular hours, day work)
4 - Student
5 - Military Service
6 - Retired/Disabled
7 - Homemaker
8 - Unemployed
9 - In controlled environment

3) Usual employment pattern, past 3 years:

- 1 - Full time (35+ hours/week)
- 2 - Part time (regular hours)
- 3 - Part time (irregular hours, day work)
- 4 - Student
- 5 - Military Service
- 6 - Retired/Disabled
- 7 - Homemaker
- 8 - Unemployed
- 9 - In controlled environment

4) Marital Status:

- 1 - Legally married
- 2 - Living with partner/cohabitating
- 3 - Widowed
- 4 - Separated
- 5 - Divorced
- 6 - Never Married

DRUG/ALCOHOL USE

	Days in Past 30 Days	Lifetime Years	ROUTE OF ADMINISTRATION				
			oral	nasal	smoking	injection	N/A
Alcohol (any use at all)	<input type="checkbox"/>						
<input type="text"/>	<input type="checkbox"/>						
<input type="text"/>	<input type="checkbox"/>						
<input type="text"/>	<input type="checkbox"/>						
<input type="text"/>	<input type="checkbox"/>						
<input type="text"/>	<input type="checkbox"/>						
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<input type="text"/>	<input type="checkbox"/>						
<input type="text"/>	<input type="checkbox"/>						
<input type="text"/>	<input type="checkbox"/>						
<input type="text"/>	<input type="checkbox"/>						
<input type="text"/>	<input type="checkbox"/>						

According to the interviewer, which substance is the major problem? (Select only one item.)

- 0 - No problem
- 1 - Alcohol (any)
- 2 - Alcohol to intoxication
- 3 - Heroin
- 4 - Methadone/LAAM (presc.)
- 5 - Methadone/LAAM (illicit)
- 6 - Opiates/analgesics
- 7 - Barbiturates
- 8 - Sed./hyp./tranq./benzos.
- 9 - Cocaine
- 10- Amph./methamph.
- 11 - Cannabis
- 12 - Hallucinogens
- 13 - Inhalants
- 14 - Nicotine
- 15 - Alcohol and Drug addiction
- 16 - Polydrug addiction

Source Completed By (Initials):

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Site Identification Number: 980101

Subject Identification Number: 0005

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done

12-Lead ELECTROCARDIOGRAM

Normal Intervals
PR: 120 - 200 msec
QT: 360 - 440 msec
QRS: 60 - 100 msec

Hour ECG	Test Type	Time (00:00-23:59)	Heart Rate Beats/minute	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal?	If Abnormal, Clinically Significant?
	12-Lead								<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

Specify Abnormality as recorded on ECG tracing

Source Completed By (Initials):

ECG1 v1

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Form Not Done

Date:
(mm/dd/yyyy)

12 LEAD ECG and DIGITAL ACQUISITION ECG

Hour	Test Type	Time (00:00-23:59)	Heart Rate (Beats/minute)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal?	If Abnormal, Clinically Significant?
<input type="text"/>		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="text"/>										

Source Completed By (Initials):

ECGDIGIT v1

Protocol Number: NIDA-CPU-0002

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Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done

Date: (mm/dd/yyyy)

12 LEAD ECG and DIGITAL ACQUISITION ECG (DAYS 0 AND 11)

Hour	Test Type	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal?	If Abnormal, Clinically Significant?
								<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

Source Completed By (Initials):

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Site Identification Number: 000001

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done

Date: (mm/dd/yyyy)

12 LEAD ECG and DIGITAL ACQUISITION ECG (DAYS 12 - 18)

Hour since last dose/Day	Test Type	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal?	If Abnormal, Clinically Significant?	
								<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

Source Completed By (Initials):

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Study Day UNSCHD

Site Identification Number: 000001

Subject Identification Number: 0001

END OF TRIAL

1) Date of last visit? (mm/dd/yyyy)

2) Was the subject terminated early from the trial? Yes No

Reason subject's participation has ended (Mark all that apply):

- Subject completed study.
- Subject was determined after enrollment to be ineligible. (Provide comments)
- Subject requested to withdraw. (Provide comments)
- Subject experienced an intercurrent illness, unrelated medical condition, or clinically significant adverse events which prompted early termination. (Complete AE form, provide comments)
- Subject terminated for administrative reasons. (Include protocol non-compliance in this category. Provide comments)
- Subject transferred to another treatment program (check all that apply)
 - Methadone
 - Drug Free
 - Inpatient Detox or Treatment
 - LAAM
 - Therapeutic Community
 - Other (specify)
- Subject was incarcerated.
- Subject became pregnant.
- Subject developed sensitivity to study agent.
- Subject was lost to follow-up.
- Subject moved from area.
- Subject died. (If subject died, a Death Report Case Report Form must be completed)
- Subject can no longer attend clinic.
- Subject no longer attends clinic.
- Subject is in a controlled environment.
- Subject is a screen failure.
- Other (Provide comments)

Comments:

Source Completed By (Initials):

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ENROLLMENT

Is subject eligible for participation based on the Eligibility Criteria? Yes No

If yes, was subject enrolled into the study? Yes No

If subject was enrolled in the study, date enrolled:
(mm/dd/yyyy)

If not enrolled, indicate reason

failed to return to clinic

declined study participation

other, specify:

Source Completed By (Initials):

ENROLL v1

Protocol Number: NIDA-CPU-0002

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Site Identification Number: 000001

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

EXCLUSION CRITERIA

Participant must not:

- 1. According to DSM-IV criteria as determined by structured clinical interview (SCID), have any current diagnosis or history of major psychiatric illness other than drug dependence or disorders secondary to drug use or be mentally or legally incapacitated.
2. According to DSM-IV criteria be dependent upon or abusing drugs other than cocaine, marijuana, nicotine, and alcohol or have physiological dependence upon alcohol requiring medical detoxification.
3. Currently be physically dependent on illicit drugs besides cocaine and marijuana as determined by the SCID. Note: The subjects that are not physically dependent on other illicit substances but during pre-study screening have a positive urine drug screen for amphetamines, barbiturates, benzodiazepines, methadone, opiates, PCP, or propoxyphene will be allowed to participate after a wash-out period and providing a negative urine drug screen.
4. Use any prescription drugs within 14 days of enrollment or non-prescription drugs within 7 days of enrollment, or if female, have used an oral contraceptive, Depo-Provera, Norplant or intrauterine progesterone contraceptive system within 30 days of enrollment.
5. Be pregnant or lactating.
6. Have a history of liver disease or of any elevation of aspartate aminotransferase (AST) or alanine aminotransferase (ALT) exceeding the upper limit of normal.
7. Have donated a unit of blood or participated in any other clinical investigation within 4 weeks of enrolling on the study.
8. Have a history of any illness, a family history of early significant cardiovascular disease, or a history of behavior, that in the opinion of the investigator might confound the results of the study or pose additional risk in administering the investigational agents to the subject.
9. Be seropositive for hepatitis B surface antigen, hepatitis C antibody, or human immunodeficiency virus (HIV) types 1 and 2.
10. Have a diagnosis of adult (i.e., 21 years or older) asthma, or chronic obstructive pulmonary disease (COPD), including those with a history of acute asthma within the past two years, and those with current or recent (past 2 years) treatment with inhaled or oral beta-agonist.

Note: All answers to EXCLUSION CRITERIA must be NO.

Source Completed By (Initials):

EXCLUS v1

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Form Not Done

Date: (mm/dd/yyyy)

FOLLOW-UP

1) Has contact been made with the subject? Yes No

If so, date: (mm/dd/yyyy)

2) If unable to reach subject, has contact been made with someone who can verify his/her status? Yes No

If yes, has the subject died? Yes No (If the subject died, a Death Report CRF must be completed)

3) If contact has not been made with the subject, explain:

4) Does subject report use of any of the following and if so, for how many days in the last week? (Check all that apply.)

Table with 4 columns: DRUG, Days Used, DRUG, Days Used. Includes checkboxes for Cocaine, Methamphetamine, Amphetamines, Benzodiazepines, Alcohol, Marijuana, Sedatives, Nicotine, Opiates, Barbiturates, None, Other.

5) Does the subject report currently receiving treatment for drug or alcohol abuse/dependence? Yes No

6) Does the subject report that he/she would take the study drug again if it were generally available for substance abuse treatment? Yes No Unknown

7) Have any adverse events occurred? Yes No

8) Have any serious adverse events occurred? Yes No (If yes, a Serious Adverse Event CRF must be completed)

9) Additional comments:

Source Completed By (Initials)

FOLLOWUP V1

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Study Day UNSCHD

Site Identification Number: 000001

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Form Not Done

HEMATOLOGY

Complete Blood Count	Std. Quantity	Standard Unit	Other Unit	Normal	Abnormal	Abnormal Significant	Not Done
Hemoglobin				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Provide comments for any abnormal value(s)

Source Completed By (Initials):

HEMAT v1

Protocol Number: NIDA-CPU-0002

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Site Identification Number: 000001

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

INCLUSION CRITERIA

Participant must:

- 1. Be between 18 and 45 years-of-age. Yes No
- 2. Be within 20% of ideal body weight and must weigh at least 45 kg. Yes No
- 3. Understand the study procedures and provide written informed consent. Yes No
- 4. Be volunteers who are dependent on or abusing cocaine according to DSM-IV criteria and are non-treatment seeking at time of study. Yes No
- 5. Currently use cocaine as determined by self report and positive urine test for BE within 30 days of the start of the study. Yes No
- 6. Be female and have a negative pregnancy test within 72 hours prior to receiving the first dose of investigational agent and agree to use one of the following methods of birth control, or be postmenopausal, have had hysterectomy or have been sterilized, or be male.
 - a. complete abstinence from sexual intercourse
 - b. diaphragm and condom by partner
 - c. intrauterine device and condom by partner
 - d. sponge and condom by partnerNote: oral contraceptives, Depo-Provera, Norplant and intrauterine progesterone contraceptive system are not allowed. Yes No
- 7. Be judged by the examining physician or his/her designee after a history and physical examination to be in good health, without clinically significant abnormalities. Yes No
- 8. Have an ECG performed that demonstrates normal sinus rhythm and no clinically significant arrhythmias. Yes No

Note: All answers to INCLUSION CRITERIA must be YES.

Source Completed By (Initials):

INCLUS v1

Protocol Number: NIDA-CPU-0002

GBR-12909 for Cocaine Dependence

Study Day UNSCHD

Site Identification Number: 000001

Subject Identification Number: 0001

Date: 11/11/2001
(mm/dd/yyyy)

Form Not Done

INFECTIOUS DISEASE ASSESSMENT

Indicate whether the laboratory value is NEGATIVE: negative test result, POSITIVE: but DOES NOT EXCLUDE subject from participation or continued study participation, POSITIVE SIGNIFICANT: significant during screening means subject is ineligible for study; significant while on study means consider reporting result as adverse event if unexpected and at least possibly related to investigational agent or early termination of the subject from study, INDETERMINANT: result was not interpretable.

<u>Infectious Disease</u>	<u>Result</u>	<u>Provide comments for any abnormal value</u>
<u>Hepatitis B surface antigen result</u>	Negative	
<u>Hepatitis B surface antibody result</u>		
<u>Hepatitis B core antibody result</u>		
<u>Hepatitis C virus antibody result</u>		
<u>HIV type 1</u>		
<u>HIV type 2</u>		

Source Completed By (Initials): fds

INFECDIS v1



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Form Not Done

INVESTIGATIONAL AGENT ADMINISTRATION

Line No.	Day of Week	Date	No. of Tablets Administered	Time Administered	Administered By

Source Completed By (Initials):

INVAGT v1

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LAB TRACKING (SCREENING AND DAYS 0-11)

Date: (mm/dd/yyyy)	Tests:	Actual Time (00:00-23:59)	Completed By (initials)
<input type="text"/>	<input type="checkbox"/> Plasma Alcohol <input type="checkbox"/> GBR 12909 Assay <input type="checkbox"/> Urine Specimen	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>

LABTRACK v1

Protocol Number: NIDA-CPU-0002

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Site Identification Number: 000001

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done

MEDICAL HISTORY

Disorder	Yes		No		If yes, specify or describe
	Yes excludes	doesn't exclude	history of disorder	Not evaluated	
1. Allergies: drug	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Allergies: other, specify <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Sensitivity to Agents/Compounds	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. History of Asthma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. Renal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. Hepatic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9. Pulmonary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10. Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11. Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12. Neurologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13. Psychiatric	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14. Dermatologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15. Metabolic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16. Hematologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17. Endocrine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
18. Genitourinary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19. Reproductive System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
20. Seizure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
21. Infectious Disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
22. Other 1, specify: <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
23. Other 2, specify: <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

24. Was major surgery ever performed?

Yes No

(If Yes, list surgeries:)

	Type of Surgery	Date of Surgery (mm/dd/yyyy)	Yes excludes	Yes doesn't exclude	No
25.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

TOBACCO HISTORY

32. Has subject used any tobacco product (e.g. cigarettes, cigars, pipe, chewing tobacco) in the past week?

Yes No

33. Has subject ever used any tobacco product for at least one year?

Yes No

34. If yes, number of years tobacco used?

COMMENTS

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0002

GBR-12909 for Cocaine Dependence

Site Identification Number: 000001

Subject Identification Number: 0001

Study Day: UNSCHD

Form Not Done

Date: (mm/dd/yyyy)

McLEAN HOSPITAL
OVERT AGGRESSION SYMPTOM CHECK LIST

Indicate with an appropriate check mark whether or not you have engaged in any of the following behaviors during -

Form with checkboxes for time periods: the past day, the past week, the past month, the past year, any time in your life.

I. VERBAL AGGRESSION

- 1. I have made loud noises, or shouted angrily
2. I have yelled mild personal insults (e.g., "You're stupid")
3. I have cursed viciously, or used foul language in anger
4. I have made clear threats of violence to myself or others

II. PHYSICAL AGGRESSION TOWARD SELF

- 1. I have picked or scratched at my skin, hit myself, pulled my hair, or hurt myself without causing any actual injury.
2. I have banged my head, hit my fist into objects, thrown myself down, or hurt myself in such a way as to inflict minor injury
3. I have made small cuts, bruises, or burns on my body, or have hurt myself in such a way as to visibly damage my skin
4. I have cut myself deeply, bit myself till I bled, inflicted internal injury, broke bones, or hurt myself in a potentially serious way

III. PHYSICAL AGGRESSION TOWARD OBJECTS

- 1. I have slammed doors, scattered my clothes, or made a mess out of anger
2. I have thrown objects down, kicked furniture without breaking it, or have marked walls
3. I have broken objects or smashed windows
4. I have set a destructive fire, or damaged valuable property

IV. PHYSICAL AGGRESSION TOWARD OTHERS

- 1. I have made threatening gestures, swung at someone, or grabbed at someone's clothing out of anger
2. I have hit, kicked pushed someone or pulled their hair, without injuring them
3. I have attacked someone, causing mild-to-moderate physical injury (bruises, sprains, welts), or threatened someone with a dangerous weapon
4. I have attacked someone, causing severe physical injury (e.g., broken bones, deep cuts, internal injury)

V. SUICIDALITY

- 1. I have daydreamed or fantasized about committing suicide
2. I have formulated a detailed suicide plan, but did not make an attempt
3. I have taken an overdose of medications, mixed alcohol and pills, or engaged in other hazardous behavior to escape from my feelings, with little concern for my personal safety, but without an absolutely certain intent to die
4. I have taken a massive overdose, tried to hang myself, or directly made a nearly lethal suicide attempt with an absolutely certain intent to die

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0002

GBR-12909 for Cocaine Dependence

Study Day UNSCHD

Site Identification Number: 000001

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Form Not Done

ABBREVIATED PHYSICAL EXAMINATION

General Exam

	Normal	Abnormal	Abnormal Significant	Not Done	If Abnormal, explain below
Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neuropsychiatric mental status	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neuropsychiatric sensory/motor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Source Completed By (Initials):

PHYEXAM2 v1

Protocol Number: NIDA-CPU-0002
GBR-12909 for Cocaine Dependence

Site Identification Number: 000001
Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done

PHYSICAL EXAMINATION

Height: inches centimeters

Weight: pounds kilograms

General Exam	Normal	Abnormal	Abnormal Significant	Not Done	If Abnormal, explain below
Oral (mouth)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Head and Neck	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Chest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lungs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen (include liver/spleen)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Extremities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Skin, Hair, Nails	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neuropsychiatric mental status	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neuropsychiatric sensory/motor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
General Appearance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Rectal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Prostate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Breast	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Genital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pelvic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0002
GBR-12909 for Cocaine Dependence

Site Identification Number: 980101
Subject Identification Number: 0005

Study Day UNSCHD

Date:
(mm/dd/yyyy)

Form Not Done

PREGNANCY

Was a pregnancy test performed?
(If no, skip to birth control method)

Yes No

IF Yes, type:

Urine Serum

Pregnancy test result:

Positive
 Negative
 Unknown
 Not applicable, subject is male

Pregnancy test comments:

Is the subject lactating?

Yes No Not Applicable

Is the subject using an acceptable method of birth control?

Yes No

What method of birth control is the subject using?

complete abstinence from sexual intercourse
 diaphragm and condom by partner
 intrauterine device and condom by partner
 sponge and condom by partner

Source Completed By (Initials):

PREGNANT v1

Protocol Number: NIDA-CPU-0002

GBR-12909 for Cocaine Dependence

Site Identification Number: 000001

Subject Identification Number: 0001

Study Day UNSCHD

PRIOR MEDICATIONS

Has the subject taken any medications in the PAST 30 DAYS?

Yes No

If yes, please list all below:

Table with 4 columns: Dose, Unit of Medication, Frequency, and Route of Administration. It lists abbreviations and their corresponding full names for each category.

Protocol Number: NIDA-CPU-0002

GBR-12909 for Cocaine Dependence

Site Identification Number: 000001

Subject Identification Number: 0001

Study Day UNSCHD

SERIOUS ADVERSE EVENT

DEMOGRAPHIC INFORMATION

Enrollment Date (mm/dd/yyyy) Gender Male Female

Date of Birth (mm/dd/yyyy)

Race

- White, not of Hispanic Origin
Hispanic or Latino
African American, Black, not of Hispanic Origin
Asian or Pacific Islander
American Indian or Alaska Native
Other, (specify):
Unknown

Height inches centimeters Weight pounds kilograms

AE/Diagnosis:

SERIOUS ADVERSE EVENT

SAE Description

SAE Description text input area

Onset Date (mm/dd/yyyy)

Reported to FDA by: Initial Date reported to FDA: (mm/dd/yyyy)

Reported to Sponsor by: Date reported to sponsor: (mm/dd/yyyy)

Reported to NIDA by: Initial Date reported to NIDA: (mm/dd/yyyy)

Severity grade mild moderate severe

Was SAE related to investigational agent?

- definitely probably possibly remotely definitely not unknown

Action taken regarding investigational agent

- none reduced dose
discontinued permanently increased dose
discontinued temporarily delayed dose

Other action(s) taken

- none
remedial therapy - pharmacologic
remedial therapy - nonpharmacologic
hospitalization (new or prolonged)

Outcome If outcome was death, a Death Report Case Report Form must be completed.

- death disability
life-threatening event congenital anomaly
hospitalization other (specify)

Concomitant Medications

Relevant tests/laboratory data, including dates

Relevant history including pre-existing medical conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

SAE resolution date (mm/dd/yyyy) or continuing

INVESTIGATIONAL AGENT ADMINISTRATION

Is the investigational agent information known? Yes No

If yes, investigational agent name

Lot number

Expiration date (mm/dd/yyyy)

Quantity

Unit Code **Other unit**

Start date (mm/dd/yyyy) **Stop date** (mm/dd/yyyy) or continuing

Route of administration

Frequency

- auricular
- inhaled
- intra-articular
- intramuscular
- intraocular
- intravenous
- nasal
- oral
- rectal
- subcutaneous
- sublingual
- transdermal
- vaginal
- unknown
- other (specify)

- single dose
- once daily
- every other day
- twice daily
- three times a day
- four times a day
- as needed
- other (specify)

Comments

Source Completed by:

Protocol Number: NIDA-CPU-0002

GBR 12909 for Cocaine Dependence

Site Identification Number: 000001

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done

Date:
(mm/dd/yyyy)

SAFTEE GI-COMBINE (Page 1)

Complete at all visits for participant's that are assigned to MM. For further instructions, see SAFTEE guidelines in the MM manual.

PATTERN	SEVERITY	DRUG RELATED	ACTION TAKEN
IS = Isolated	MN = Minimal	N = No	N = None
IN = Intermittent	MI = Mild	DR = Dose-response	IS = Increased surveillance
CO = Continuous	MO = Moderate	TO = Timing of onset	C = Contra active RX
	S = Severe	K = Known drug effect	SU = Suspend RX
		O = Other (specify)	DC = Discontinue RX
		X = Don't Know	O = Other
			R = Dose Reduction
			I = Dose Increased

Source Completed By (Initials):

SAFTEE1 v1

Protocol Number: **NIDA-CPU-0002**
 BR 12909 for Cocaine Dependence

Site Identification Number: **980101**
 Subject Identification Number: **0001**

Study Day **UNSCHD**

Form Not Done

Date:
 (mm/dd/yyyy)

SAFTEE GI-COMBINE (Page 2)

Complete at all visits for participants that are assigned to MM. For further instructions, see SAFTEE guidelines in the MM manual.

PATTERN	SEVERITY	DRUG RELATED	ACTION TAKEN
IS = Isolated IN = Intermittent CO = Continuous	MN = Minimal MI = Mild MO = Moderate S = Severe	N = No DR = Dose-response TO = Timing of onset K = Known drug effect O = Other (specify) X = Don't Know	N = None IS = Increased surveillance C = Contra active RX SU = Suspend RX DC = Discontinue RX O = Other R = Dose Reduction I = Dose Increased

Study Specific Events	EVENT	Date of Onset (Month) (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
1. Nausea	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Drug Related Specify:	<input type="text"/>		Description*	<input type="text"/>		
2. Vomiting	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Drug Related Specify:	<input type="text"/>		Description*	<input type="text"/>		
3. Diarrhea	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Drug Related Specify:	<input type="text"/>		Description*	<input type="text"/>		
4. Abdominal Pain	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Drug Related Specify:	<input type="text"/>		Description*	<input type="text"/>		
5. Decreased Appetite	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Drug Related Specify:	<input type="text"/>		Description*	<input type="text"/>		

Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
6. Increased Appetite								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
7. Headache								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
8. Dizziness								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
9. Fatigue								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
10. Nervousness/anxiety								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
11. Insomnia								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
12. Somnolence								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
13. Depression**								
	<u>Drug Related Specify:</u>				<u>Description*</u>			

Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
14. Itching								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
15. Rash								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
16. Decreased Libido								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
17. Increased Libido								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
18. Missed menses								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
19. Significant Lab Abnormalities (describe)								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
20. Other (describe)								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
Study Specific Events	EVENT	Date of Onset (Month) (Day)		Duration (Days)	Pattern	Severity	Drug Related	Action Taken
21. Other (describe)								
	<u>Drug Related Specify:</u>				<u>Description*</u>			

<u>Study Specific Events</u>	<u>EVENT</u>	<u>Date of Onset</u>		<u>Duration</u>	<u>Pattern</u>	<u>Severity</u>	<u>Drug Related</u>	<u>Action Taken</u>
		<u>(Month)</u>	<u>(Day)</u>	<u>(Days)</u>				
22. Other (describe)								
	<u>Drug Related Specify:</u>				<u>Description*</u>			
<u>Study Specific Events</u>	<u>EVENT</u>	<u>Date of Onset</u>		<u>Duration</u>	<u>Pattern</u>	<u>Severity</u>	<u>Drug Related</u>	<u>Action Taken</u>
		<u>(Month)</u>	<u>(Day)</u>	<u>(Days)</u>				
23. Other (describe)								
	<u>Drug Related Specify:</u>				<u>Description*</u>			

Source Completed By (Initials):

SAFTEE2 v1

Protocol Number: NIDA-CPU-0002

GBR-12909 for Cocaine Dependence

Study Day UNSCHD

Site Identification Number: 000001

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Form Not Done

SCID WORKSHEET

AXIS I - Diagnosis

Please list all CURRENT and PAST Substance Abuse or Dependence Diagnoses, OTHER CURRENT, AND OTHER PAST Diagnoses (Include DSM-IV code).

Line No.	Axis I Diagnoses Type	DSM-IV Code	Diagnosis

Source Completed By (Initials):

SCID v1

Protocol Number: NIDA-CPU-0002

GBR-12909 for Cocaine Dependence

Study Day UNSCHD

Site Identification Number: 000001

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Form Not Done

**COLLECTION OF URINE SPECIMENS
FOR GBR 12909 ELIMINATION PHARMACOKINETICS**

<u>Time</u>	<u>Start Time</u> (00:00 - 23:59)	<u>Stop Time</u> (00:00 - 23:59)	<u>Total Volume</u> <u>Collected</u>
			ml
			ml
			ml

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0002
GBR-12909 for Cocaine Dependence

Site Identification Number: 980101
Subject Identification Number: 0005

Study Day UNSCHD

Form Not Done

Date:
 (mm/dd/yyyy)

URINALYSIS

Indicate whether the laboratory value is **NORMAL**: within normal limits, **ABNORMAL**: outside of normal limits but not clinically significant, **ABNORMAL SIGNIFICANT**: significant during screening means subject is ineligible for study; significant while on study means consider reporting result as adverse event if unexpected and at least possibly related to investigational agent, or requires early termination from study.

Dipstick Urinalysis:

Specific gravity
pH

Color
Appearance

Lab	Levels	Result	Comments for Abnormal Values
Blood	<input type="text"/>	<input type="text"/>	<input type="text"/>
Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>
Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>
Ketones	<input type="text"/>	<input type="text"/>	<input type="text"/>
Leukocytes	<input type="text"/>	<input type="text"/>	<input type="text"/>
Nitrite	<input type="text"/>	<input type="text"/>	<input type="text"/>
Bilirubin	<input type="text"/>	<input type="text"/>	<input type="text"/>
White Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>
Red Blood Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>
Epithelial Cells	<input type="text"/>	<input type="text"/>	<input type="text"/>
Casts	<input type="text"/>	<input type="text"/>	<input type="text"/>

Source Completed By (Initials):

URINE v1

Protocol Number: NIDA-CPU-0002

GBR-12909 for Cocaine Dependence

Study Day UNSCHD

Site Identification Number: 000001

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Form Not Done

URINE TOXICOLOGY

Urine temperature within expected range?

Yes No Unknown (96.4 < or = T < or = 100.4 F)

Drug/Test	Positive	Negative	Not Done
Amphetamines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0002

GBR-12909 for Cocaine Dependence

Study Day UNSCHD

Site Identification Number 000001

Subject Identification Number 0001

Date: (mm/dd/yyyy)

Form Not Done

VITAL SIGNS (Days 1-11)

Hour	Time (00:00 - 23:59)	Temp (oral) Fahrenheit or Celcius	Resp. Rate (Breaths/Min)	Pulse Rate (Beats/Min)	Blood Pressure (systolic) / (diastolic)	Comp. By: (Initials)
		<input type="checkbox"/> <input type="checkbox"/>			/	
		<input type="checkbox"/> <input type="checkbox"/>			/	
		<input type="checkbox"/> <input type="checkbox"/>			/	
		<input type="checkbox"/> <input type="checkbox"/>			/	
		<input type="checkbox"/> <input type="checkbox"/>			/	
		<input type="checkbox"/> <input type="checkbox"/>			/	
		<input type="checkbox"/> <input type="checkbox"/>			/	
		<input type="checkbox"/> <input type="checkbox"/>			/	

Protocol Number: NIDA-CPU-0002

GBR-12909 for Cocaine Dependence

Site Identification Number:

Subject Identification Number:

Study Day

Date:

Form Not Done

VITAL SIGNS (Screening / Days 12-47)

Time (00:00 - 23:59)	Temp (oral) Fahrenheit or Celcius <input type="checkbox"/> F <input type="checkbox"/> C	Resp. Rate (Breaths/Min)	Pulse Rate (Beats/Min)	Blood Pressure (systolic) / (diastolic)	Comp.By: (Initials)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/>	<input type="text"/>

000001

0001

(mm/dd/yyyy)

Comp.By:
(Initials)

VITALS2 v1